PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference E-2211/04	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP03/12087	International filing date *(day/month/year)* 30.10.2003	Priority date *(day/month/year)* 04.11.2002
International Patent Classification (IPC) or both national classification and IPC A61C1/00		
Applicant UNIVERSITA' DEGLI STUDI DI PADOVA et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
01.06.2004	08.03.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Salvatore, C Telephone No. +49 89 2399-7194

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/12087

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-3, 5-9	as originally filed
4	received on 29.10.2004 with letter of 29.10.2004

Claims, Numbers

1-11	received on 29.10.2004 with letter of 29.10.2004

Drawings, Sheets

1/1	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 1-6

   because:

   ☒ the said international application, or the said claims Nos. Claims 1-6 are steps of a surgical method and violate Rule 67(1)(iv) PCT relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	7-11
	No:	Claims	
Inventive step (IS)	Yes:	Claims	7-11
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	7-11
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

No opinion can be expressed with regards to claims 1-6 because they are clearly steps in a surgical method. It is clear from the claims and the description that the procedure *"for treating hard tissue"* as claimed in claims 1-6 is performed in the mouth of the patient and is a clear violation of Rule 67(1)(iv) PCT.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: WO 00/62694 A (ALTSHULER GREGORY) 26 October 2000 (2000-10-26)
D2: WO 02/42719 A (DOMANKEVITZ YACOV ; ANDERSON R ROX (US); GEN HOSPITAL (US)) 30 May 2002 (2002-05-30)
D3: US-A-6 156 030 (NEEV JOSEPH) 5 December 2000 (2000-12-05)
D4: WO 99/49937 A (GEN HOSPITAL CORP ; PALOMAR MEDICAL TECHNOLOGIES I (US)) 7 October 1999 (1999-10-07)
D5: US-A-5 456 603 (KOWALYK KENNETH ET AL) 10 October 1995 (1995-10-10)
D6: US-A-4 951 663 (L ESPERANCE JR FRANCIS A) 28 August 1990 (1990-08-28)
D7: US-A-5 713 891 (POPPAS DIX P) 3 February 1998 (1998-02-03)

Document D1 is regarded as being the closest prior art to the subject-matter of claim 7, and shows an apparatus for treating hard tissues comprising :

a source of laser light having a variable fluence, an optical system for focussing the laser light.

The subject-matter of claim 7 differs from this known device in that the laser source in D1 is not disclosed as being a semiconductor laser, in fact the diode laser is only used to pump another laser such as a YAG laser. The other difference is that D1 does not disclose the use of a chromophorous agent.

There are two clear problems solved by these differences, namely that of selective absorption of the laser light by the chromophorous agent and hence more efficient treatment of the site; and the other is the more compact device obtained by using only a laser diode as opposed to a pumped laser source. The former problem is not deemed inventive in view of documents D5-D7 and also common knowledge in the field relating to the use of chromophorous agents. However, neither the problem of compactness of the device nor its resolution is anticipated or implied in any of the prior arts.

Also in the light of D5, which is considered a very closely related document and which discloses the laser source and the use of a chromophorous agent, no mention is made as to the use of a semiconductor laser in the list of possible lasers to be used in the invention. Documents D1-D7 are thus only representative of the general state of the art.

For the reasons above, claim 7 is thus considered to be novel and inventive and have industrial applicability.
Claims 8-11 are dependent on claim 7 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

and this prevents use of this system in procedures on tooth tissue, since the local maximum of the absorption of this tissue, which is around 3pm, cannot be used. The instrument is therefore limited to polymerization of the applied composite materials and is not applied in the ablation of hard surfaces of teeth.

Finally, it should also be noted that problems similar to the ones noted above for the dental sector can also occur in other fields of surgery, when it is necessary to act in order to treat other hard tissues, such as for example bones.

Disclosure of the invention

The aim of the present invention is to provide a method that uses the radiation of a semiconductor or diode laser to treat hard tissues, such as for example the surfaces of teeth or bones, in which absorption of the laser radiation by the tissue is sufficient and limited to the surface of the tissue to be treated, so as to not allow said radiation to penetrate to the interior, consequently causing pain and/or degradation of sensitive biological tissues.

Within this aim, an object of the invention is to provide an apparatus for providing the method described above that is easy to handle and compact but at the same time reliable and highly efficient.

Another object of the invention is to limit the high costs entailed by the technologies of the prior art.

This aim and these and other objects that will become better apparent hereinafter are achieved by the method according to claim 1 and by the apparatus according to claim 7.

Brief Description of the Drawings

Further characteristics and advantages of the present invention will become better apparent hereinafter from the following detailed description thereof, taken with the accompanying drawing, wherein the only figure is a block diagram of the apparatus of the invention.

CLAIMS

1. A method for treating hard tissues, comprising the steps of:

-- generating a radiation from a laser source;

-- focusing the radiation on the surface of the tissue by means of a suitable optical system;

-- exceeding a fluence threshold of the laser radiation as a function of the tissue to be treated; and

-- applying a chromophorous agent with high absorption at the wavelength of the laser to a region of a tissue to be treated, so as to have predominant absorption at the surface of the tissue;

characterized in that the laser radiation is generated from a semiconductor laser source having a power of more than 100 W and a fluence threshold between 20 and 100 J/cm^2 and emitting a laser radiation having a wavelength comprised between 600 and 1000 nm.

2. The method according to claim 1, characterized in that the laser radiation is a pulsed radiation, the duration of the pulse being comprised between 10 and 50,000 μs.

3. The method according to claim 1, characterized in that the laser radiation is conveyed by means of a guided optical system.

4. The method according to 3, characterized in that the guided optical system is an optical fiber.

5. The method according to claim 1, characterized in that the focusing of the radiation in output from the optical fiber on the surface of the tissue is achieved by means of a system of lenses or mirrors.

6. The method according to claim 1, characterized in that the chromophorous agent is sprayed onto the tissue by means of an aerosol.

7. An apparatus for treating hard tissues, comprising:

-- a source of laser light emitting a radiation having a variable fluence threshold;

-- an optical system for focusing the laser light on the surface to be treated; and

-- a system for applying a chromophorous agent to a surface of a tissue;

characterized in that the source of laser light contains at least one semiconductor laser having a fluence threshold between 20 and 100J/cm^2 and a power of more than 100 W and emitting a laser radiation having a wavelength comprised between 600 and 1000 nm.

8. The apparatus according to claim 7, characterized in that the laser radiation is a pulsed radiation; the duration of the pulse being comprised between 10 and 50,000 μs.

9. The apparatus according to claim 7, characterized in that the laser radiation is conveyed by means of a guided optical system.

10. The apparatus according to claim 9, characterized in that the guided optical system is an optical fiber.

11. The apparatus according to claim 10, characterized in that the optical fiber has a diameter of 5 to 2000 μm.